K063437

APR - 4 2008

Monobind, Inc.

510(k) Safety and Effectiveness Summary

Re:	510-K Summary
Date:	October 27, 2006.
Submitter:	Monobind Inc, 100 North Pointe Lake Forest. CA 92630.
Contact:	Dr. Jay Singh
Trade Name:	AccuBind™ Neo-TSH Microwell Elisa Kit.
Regulation Number	862.1690
Product Code	JLW
Common Name:	Neonatal TSH Elisa
Classification Name:	Thyroid Stimulating Hormone Test System
Predicate Device:	Neonatal TSH RIA Kit (I^{-125}) 510(k)# K772192

Device Description:

The Monobind AccuBind™ Neonatal TSH Elisa Assay is a solid phase two-site immunoenzymometric assay based on the direct sandwich technique in which two specific antibodies are directed against two separate antigenic determinants on the hTSH molecule.

In this method, TSH dried whole blood calibrator, patient specimen or control is first added to a streptavidin coated well. Elution buffer containing biotinylated monoclonal antibodies are added and the reactants mixed. Reaction between the biotinylated Anti-TSH and the TSH in the dried blood spot forms a complex that binds to the streptavidin coated to the well due to the inherent affinity of streptavidin and biotin.

After the completion of the first incubation period, excess reactants are washed off via a wash step and the enzyme conjugate (another specific anti-TSH antibody linked to an enzyme) is added to the Ag-Ab complex deposited on the plastic surface. The enzyme labeled Anti-TSH antibody binds to the TSH making a sandwich complex with two antibodies bound to the antigen during a second incubation. The microplate is washed to remove unreacted enzyme. Finally, the activity of the enzyme present on the surface of the well is quantitated by reaction with a suitable substrate to produce color.

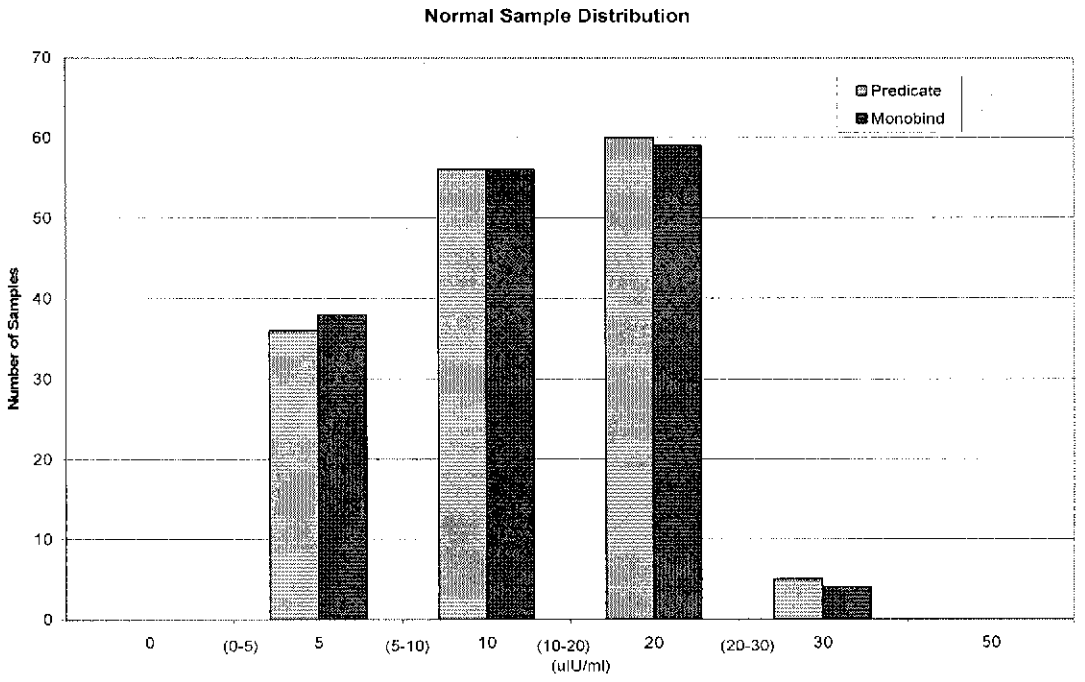
Intended Use:

The Monobind AccuBind Neo-TSH Microwell Elisa Assay is an *in vitro* diagnostic test system for the quantitative determination of thyroid stimulating hormone (TSH) in human whole blood dried on Whatman 903 filter paper. It is intended to be used to screen newborns for congenital hypothyroidism.

Equivalence Comparison:

Data submitted in this 510-K Premarket notification is correct and has been compared to be substantially equivalent to a 510-K cleared, commercially available predicate device in the market, marketed by Diagnostics Products Corporation, Los Angeles. California, distributed as Neonatal TSH RIA Kit.

The hTSH concentrations were measured in 158 newborn samples with AccuBind™ Neo-TSH microwell Elisa kit and DPC IRMA (RIA) kit. The total range when measured with the AccuBind Neo-TSH Elisa kit was 0.7 to 25.52 µIU/ml with a mean of 8.31 µIU/ml. The total range for the DPC RIA method was 0.61 to 26.6 µIU/ml with a mean of 8.87 µIU/ml of whole blood. The frequency distribution are shown in the following figure.



The device is an *in vitro diagnostic* test kit. And, the results obtained with are to be interpreted in conjunction with other relevant information available to the clinicians.

This device has no environmental impact.

The performance data and clinical data are on file and are available to any qualified individual upon request. *Monobind* is responsible and attests that all information submitted is true and authentic to the best of our knowledge.

Sincerely,

Jay Singh
Director R&D.

Frederick Jerome
President

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

APR - 4 2008

Monobind, Inc.
c/o Dr. Jay Singh
Director R & D
100 N. Pointe Drive
Lake Forest, CA 92630

Re: k063437
Trade/Device Name: AccuBind Neo-TSH Microwell Elisa Assay
Regulation Number: 21 CFR 862.1690
Regulation Name: Thyroid stimulating hormone test system.
Regulatory Class: Class II
Product Code: JLW
Dated: March 25, 2008
Received: March 27, 2008

Dear Dr. Singh:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0490. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address at http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Jean M. Cooper, M.S., D.V.M.

Jean M. Cooper, M.S., D.V.M.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K063437

Device Name: AccuBind™Neo-TSH Microwell Elisa Assay

Indications For Use: The Monobind AccuBind Neo-TSH Microwell Elisa Assay is an *in vitro* diagnostic test system for the quantitative determination of thyroid stimulating hormone (TSH) in human whole blood dried on Whatman 903 filter paper. It is intended to be used to screen newborns for congenital hypothyroidism.

Prescription Use ☒ AND/OR Over-The-Counter Use

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

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